

7. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

8. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

9. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

10. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of the approved New Drug Application (“NDA”) for Yaz®/Beyaz®.

11. Defendant BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal place of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

12. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under the name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

13. Defendant BAYER PHARMA AG is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

14. Defendant, BAYER PHARMA AG’s headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

15. Defendant, BAYER PHARMA AG is the current owner of the patent(s) relating to the oral contraceptives, Yaz® and Beyaz®.

16. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

17. Defendant BAYER AG is the parent/holding company of all other named Defendants.

18. Defendant, BAYER AG’s headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

19. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories Inc., and Berlex, Inc.,

Bayer Pharma AG and Bayer AG, shall be referred to herein individually by name or jointly as “Defendants.”

20. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organization units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents and representatives and any and all other persons acting on their behalf.

21. At all times mentioned herein, each Defendant was the agent, servant, partner, predecessor in interest, aider and abetter, co-conspirator and joint-venturer or each of the remaining Defendants herein and was at all times operative and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

22. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce through the United States, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives Yaz® and Beyaz®.

II. JURISDICTION AND VENUE

23. Plaintiff alleges damages in excess of one hundred fifty thousand dollars (\$150,000.00), exclusive of costs and interests.

24. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds \$150,000.00, exclusive of interest and costs.

25. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this District, including, but not limited to, the development, design, licensing, labeling, manufacturing and/or marketing of the defective drug, as well as Defendant's fraud and conspiracy to actively conceal and/or misrepresent information concerning the safety and efficacy of Yaz® and Beyaz® with the intention and specific desire to mislead the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff.

III. FACTUAL ALLEGATIONS

A. Nature of the Case

26. Plaintiff brings this case against Defendants for damages associated with Plaintiff Dana Dougherty's ingestion of the pharmaceutical drug Yaz® and Beyaz®. (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered a deep vein thrombosis on September 7, 2011 as a direct result of her use of Yaz®.

B. The Dangerous Drug(s)

27. Yasmin, Yaz® and Beyaz® are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

28. Yasmin received FDA approval first in 2001. It is a combination of drospirenone, a progestin, and ethinyl estradiol, an estrogen.

29. Yaz received FDA approval first in 2006. It is essentially the same as Yasmin, with the only difference being a slightly smaller amount of ethinyl estradiol.

30. Beyaz received approval from the FDA in 2010 and is essentially the same as Yaz with the only difference being Beyaz contains a folate supplement.

31. Yasmin, Yaz® and Beyaz® (collectively referred to as "the drugs") are indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.

32. Combination birth control pills are referred to as combined hormonal oral contraceptives.

33. The difference between Yasmin, Yaz® and Beyaz® and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

34. Yaz® and Beyaz® use of drospirenone, a diuretic, creates unique risks compared to other oral contraceptives and is known to cause problems including deep vein thrombosis.

35. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yaz® and Beyaz® and the significantly increased risk of deep vein thrombosis.

36. Despite the wealth of scientific information available, Defendant ignored the correlation between the use of Yaz® and Beyaz® and the significantly increased risk of deep vein thrombosis and still promoted, sold, advertised, and marketed the use of Yaz® and Beyaz® without sufficient warnings.

37. Yasmin®, Yaz® and Beyaz® contain the Fourth Generation progestin called drospirenone which is associated with increased risk of deep vein thrombosis.

C. Over-Promotion of Yasmin® Yaz® and Beyaz®

38. Defendants market Yasmin®, Yaz® and Beyaz® as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

39. However, because Yasmin® Yaz® and Beyaz® contain the fourth generation progestin drospirenone which is a diuretic they present additional health risks not associated with other birth control pills.

40. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted the fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

41. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

42. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

43. More recently, Defendants advertised that its product Yaz® was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

44. Defendants also advertised that Yaz® contained the added benefit of preventing or reducing acne.

45. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

46. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

47. Indeed, the FDA felt Defendants' over promotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

48. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

49. Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this complaint.

50. As a result of the manufacture, marketing, advertising, promotion, distribution, and the sale of Yasmin® Yaz® and Beyaz® without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

51. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin® Yaz® and Beyaz® Plaintiff's medical provider prescribed her and she ingested Yaz® and Beyaz®.

D. Plaintiff's Use and Resulting Injuries

52. In or around September 7, 2011 while taking Yaz®/Beyaz® Plaintiff suffered a deep vein thrombosis in her right leg requiring inpatient hospitalization and continuing medical treatment.

53. As a direct and proximate result of using Yaz®/Beyaz®, Plaintiff suffered the injuries described above.

54. Prior to Plaintiff's use of Yaz®/Beyaz®, Defendants knew or should have known that use of Yaz®/Beyaz® created a higher risk of deep vein thrombosis than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

55. Therefore, at the time Plaintiff used Yaz®/Beyaz®, Defendants knew or should have known that the use of Yaz®/Beyaz® created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

56. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz®/Beyaz®, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

57. Had Plaintiff and/or her health care providers known the risks and dangers associated with Yaz®/Beyaz®, she would not have used Yaz®/Beyaz® and would not have suffered injuries described above.

58. As a direct and proximate result of her use of Yaz®/Beyaz®, Plaintiff suffered physical injury, including but not limited to, conscious pain and suffering, as a result of deep vein thrombosis.

59. As a direct and proximate result of her use of Yaz®/Beyaz®, Plaintiff has suffered and will continue to suffer pecuniary and other losses including, but not limited to, risks in future pregnancies.

60. As a direct and proximate result of Plaintiff's use of Yaz®/Beyaz® and resulting injuries, her deep vein thrombosis, Plaintiff Dana Dougherty, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm.

IV. CAUSES OF ACTION

COUNT I FRAUDULENT CONCEALMENT

61. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

62. Prior to Plaintiff's use of Yaz®/Beyaz® and during the period in which Plaintiff actually used Yaz®/Beyaz®, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yaz®/Beyaz®, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, and the unique deep vein thrombosis dangers. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Yaz®/Beyaz® strong.

63. Defendants fraudulently concealed safety issues with Yaz®/Beyaz® in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use Yaz®/Beyaz®.

64. At the time Defendants concealed the fact that Yaz®/Beyaz® was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Yaz®/Beyaz®.

65. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of Yaz®/Beyaz®.

66. As a direct and proximate result of Defendants' malicious and or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries.

67. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

68. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yaz®/Beyaz® as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the Healthcare community and the general public. Without full knowledge of the dangers of Yaz®/Beyaz®, Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by Yaz®/Beyaz® had a valid claim.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT II STRICT LIABILITY

69. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

70. At the time of Plaintiff's injury, Defendants' pharmaceutical, Yaz®/Beyaz®, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

71. The Yaz®/Beyaz® used by Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

72. Plaintiff did not misuse or materially alter the Yaz®/Beyaz®.

73. Defendants are strictly liable for Plaintiff's injury in the following ways:

- a. The pharmaceutical Yaz®/Beyaz® as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell Yaz®/Beyaz®;
- c. Defendants failed to warn and/or place adequate warnings and instructions on Yaz®/Beyaz®;
- d. Defendants failed to adequately test Yaz®/Beyaz®;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Yaz®/Beyaz®; and
- f. A feasible alternative design existed that was capable of preventing Plaintiff's injury.

74. Defendants' actions and omissions were the direct and proximate cause of Plaintiff's injury.

75. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT III BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

76. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

77. At the time Defendants marketed, distributed and sold Yaz®/Beyaz® to Plaintiff, Defendants warranted that Yaz®/Beyaz® was merchantable and fit for the ordinary purposes for which it was intended.

78. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

79. Yaz®/Beyaz® was not merchantable and fit for its ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this complaint.

80. Plaintiff reasonably relied on Defendants' representations that Yaz®/Beyaz® was safe and free of defects and was a safe means of birth control.

81. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injury.

82. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, and warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

83. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

84. Defendants sold Yaz®/Beyaz® with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

85. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

86. Yaz®/Beyaz® was not fit for the particular purpose of a safe birth control pill without serious risk of personal injury, which risk is much higher than other birth control pills.

87. Plaintiff reasonably relied on Defendants' representations that Yaz®/Beyaz® was safe and effective for use as a birth control method.

88. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiff's injury.

89. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

90. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT FAILURE TO WARN

91. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

92. Before Plaintiff used Yaz®/Beyaz®, and during the period in which she used it, Defendants knew or had reason to know that Yaz®/Beyaz® was dangerous and created an unreasonable risk of bodily harm to consumers.

93. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Yaz®/Beyaz® likely to be dangerous.

94. Despite the fact that Defendants knew or had reason to know that Yaz®/Beyaz® was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Yaz®/Beyaz® likely to be dangerous.

95. The Plaintiff's injury was a direct and proximate result of Defendants' failure to warn of the dangers of Yaz®/Beyaz®.

96. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VI NEGLIGENCE

97. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

98. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of Yaz®/Beyaz®, including a duty to assure that the product did not cause unreasonable, dangerous side effects to users.

99. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of Yaz®/Beyaz® in that Defendants' knew or should have known that the drug created a high risk of unreasonable harm.

100. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Yaz®/Beyaz® in that, among other things, they:

a. Failed to use due care in designing and manufacturing Yaz®/Beyaz® so as to avoid the aforementioned risks to individuals;

b. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated its use, and the comparative severity and duration of such adverse effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

- c. Failed to provide adequate training and instruction to medical care providers for appropriate use of Yaz®/Beyaz®;
- d. Placed an unsafe product into the stream of commerce; and
- e. Were otherwise careless or negligent.

101. Despite the fact that Defendants knew or should have known that Yaz®/Beyaz® caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market Yaz®/Beyaz® to consumers, including the medical community and Plaintiff.

102. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VII NEGLIGENT MISREPRESENTATION

103. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

104. Prior to Plaintiff first using Yaz®/Beyaz® and during the period in which she used Yaz®/Beyaz®, Defendants misrepresented that Yaz®/Beyaz® was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of Yaz®/Beyaz®, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life threatening.

105. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

106. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with Yaz®/Beyaz®, that their representations regarding Yaz®/Beyaz® were false, and that they had a duty to disclose the dangers of Yaz®/Beyaz®.

107. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing Yaz®/Beyaz®.

108. Plaintiff justifiably relied on Defendants' representations and nondisclosures by purchasing and using Yaz®/Beyaz®.

109. Defendants' misrepresentations and omissions regarding the safety and efficacy of Yaz®/Beyaz® was the direct and proximate cause of Plaintiff's injuries.

110. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VIII BREACH OF EXPRESS WARRANTY

111. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

112. Defendants expressly warranted that Yaz®/Beyaz® was safe and effective to members of the consuming public, including Plaintiff.

113. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

114. Defendants marketed, promoted and sold Yaz®/Beyaz® as a safe method of birth control.

115. Yaz®/Beyaz® does not conform to these express representations because Yaz®/Beyaz® is not safe and has serious side effects, including death.

116. Defendants breached their express warranty in one or more of the following ways:

- a. Yaz®/Beyaz®, as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to warn and/or place adequate warnings and instructions on Yaz®/Beyaz®;

c. Defendants failed to adequately test Yaz®/Beyaz®; and

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Yaz®/Beyaz®.

117. Plaintiff reasonably relied upon Defendants' warranty that Yaz®/Beyaz® was safe and effective when she purchased and used the medication.

118. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

119. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, and warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT IX FRAUD

120. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

121. Defendants widely advertised and promoted Yaz®/Beyaz® as a safe and effective medication.

122. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

123. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants' touted Yaz®/Beyaz® as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

124. Had Plaintiff been aware of the hazards associated with Yaz®/Beyaz®, Plaintiff would not have consumed the product that led proximately to Plaintiffs adverse health effects.

125. Defendants' advertisements regarding Yaz®/Beyaz® made material

misrepresentations to the effect that Yaz®/Beyaz® was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and consume Yaz®/Beyaz®.

126. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Yaz®/Beyaz® with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT X VIOLATION OF DECEPTIVE TRADE PRACTICES ACT

127. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

128. Defendants violated the Deceptive Trade Practices Act ("DTPA") of the Commonwealth of Pennsylvania where plaintiff resides by use of false and misleading misrepresentations or omissions of material fact in connection with marketing, promotion and sale of Yaz®/Beyaz®.

129. Defendants communicated the purported benefits of Yaz®/Beyaz® while failing to disclose the serious and dangerous side effects related to the use of Yaz®/Beyaz® with the intent that consumers, like the plaintiff and her health care providers, rely upon omissions and misrepresentations and purchase and/or prescribe Yaz®/Beyaz®.

130. As a result of the violation of DTPA, defendants caused plaintiff to be prescribed and to use Yaz®/Beyaz®, causing severe injuries and damages as described herein.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of \$350,000.00;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Attorneys' fees, expenses, and costs of this action;
4. Punitive damages in excess of twice the compensatory damages award;
5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

Respectfully submitted,

MCVAN & WEIDENBURNER

BPM3633

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